

CLAIMS

5 **What is claimed:**

1. A stable formulation of a biologically active protein useful for aerosol delivery to the respiratory tract of a patient in need of treatment comprising:

(a) a carrier liquid comprising from about 10% to from about 100% V/V water and from about 0% to from about 90% V/V of an organic liquid;

(b) a biologically effective amount of a protein suspended or dissolved in a carrier liquid; and

(c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent suspended or dissolved in said carrier liquid.

15 2. A stable suspension according to claim 1 wherein said formulation contains from about 0.1% to about 5.0% W/V of a pharmaceutically acceptable excipient.

20 3. A stable formulation according to claim 1 wherein said biologically active protein is selected from the group comprising enzymes, antibodies, antigens, hormones and cytokines.

25 4. A stable formulation according to claim 3 wherein said therapeutically active protein is a hormone.

5. A stable formulation according to claim 4 wherein said therapeutically active protein is insulin.

30 6. A stable formulation according to claim 3 wherein said therapeutically active protein is a cytokine.

7. A stable formulation according to claim 6 wherein said therapeutically active protein is Factor VIII.

8. A stable formulation according to claim 1 wherein said carrier liquid contains from about 20% to from about 100% water V/V.

9. A stable formulation according to claim 8 wherein said carrier liquid  
5 comprises about 50% water and about 50% organic solvent.

10. A stable formulation according to claim 1 wherein said organic liquid is ethanol, isopropyl alcohol, butanol, isobutanol, perfluorocarbons, glycerol, polyethylene glycol, propylene glycol, or combinations thereof.

11. A stable formulation according to claim 10 wherein said organic liquid is ethanol, glycerol, polyethylene glycol, propylene glycol, or combinations thereof.

15. 12. A stable formulation according to claim 1 wherein said sugar moiety is selected from the group consisting of trehalose, sucrose, glucose, maltose, and galactose.

20. 13. A stable formulation according to claim 1 wherein said protein is suspended in the carrier liquid.

14. A stable formulation according to claim 13 wherein the particle size of said protein in suspension is from about 0.01  $\mu$  to about 10.0  $\mu$ .

25. 15. A stable formulation according to claim 14 wherein the particle size of said protein in suspension is from about 5.0  $\mu$  to about 10.0  $\mu$ .

16. A stable formulation according to claim 15 wherein the particle size of said protein in suspension is from about 0.01  $\mu$  to about 3.0  $\mu$ .

30. 17. A stable formulation according to claim 2 wherein said formulation contains from about 0.1% to about 5.0% of a pharmaceutically acceptable excipient.

18. A stable formulation according to claim 1 wherein said protein is dissolved in the carrier liquid.

19. A stable formulation according to claim 18 wherein said formulation contains from about 0.1% to about 5.0% of a pharmaceutically acceptable excipient.

20. A stable formulation of a biologically active protein useful for aerosol delivery to the respiratory tract of a patient in need of treatment comprising:

- (a) a carrier liquid which is from about 20% to from about 30% V/V water and from about 70% to from about 80% V/V of ethanol;
- (b) a biologically effective amount of a protein suspended or dissolved in a carrier liquid; and
- (c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent elected from the group consisting of C8-trehalose, C16-trehalose, C8-glycopyranoside and C12-glycopyranoside.

21. A stable formulation of a biologically active protein useful for aerosol delivery to the respiratory tract of a patient in need of treatment comprising:

- (a) a carrier liquid which is an aqueous liquid;
- (b) a biologically effective amount of a protein suspended or dissolved in said carrier liquid; and
- (c) a stabilizing effective amount of a derivatized carbohydrate stabilizing agent elected from the group consisting of C8-trehalose, C16-trehalose, C8-glycopyranoside and C12-glycopyranoside.